REMARKS

Status of Claims

Claim 23 is currently amended.

Claim 32 has been canceled.

Thus, claims 23-31 and 33-42 are currently pending in this application.

Applicant hereby requests further examination and reconsideration of the presently claimed application.

Specification

Applicant has corrected the abstract to meet the word length requirement. No new matter is introduced by way of this correction.

Claims Rejection – 35 U.S.C. § 112 1st

Claims 23-42 stand rejected under 35 U.S.C. § 112 first paragraph as not reasonably providing enablement for destroying, inactivating, or inhibiting the growth of any and all viruses. Applicant has amended claim 23 to include the limitations of claim 32 which recites that the viruses have "a lipid envelope." Applicant directs the Examiner's attention to the instant application which recites:

> "Influenza viruses, including A/Sydney/5/97 and viruses which fall within the A and B types of influenza, Urbani SARS and Herpes Simplex virus type-1 **all possess a lipid envelope**. Other examples of viruses having a lipid envelope include coronaviruses (one of which is Urbani SARS), Herpes Simplex Virus type-2 (HSV-2), Human Immunodeficiency Virus (HIV), Hepatitis B, Hepatitis C, West Nile virus, Vesicular stomatitis virus, Sindbis virus and Sendai virus." (Page 4, paragraph 24)

Applicant contends the specification provides enablement for the destruction, inactivation, or inhibition of viruses containing a lipid envelope and respectfully request the rejection be withdrawn.

Claims Rejection – 35 U.S.C. § 112 2nd

Claims 23-42 stand rejected under 35 U.S.C. § 112 second paragraph as being indefinite for failing to provide an active method step to distinguish the prior art over the instant invention. Applicant has amended claim 23 to recite:

> "A method comprising **administering** p-menthane-3,8-diol (PMD) to destroy, inactivate, or inhibit growth or reproduction of a virus wherein the virus has a lipid envelope."(Claim 23, emphasis added)

Thus, Applicant respectfully requests the rejection be withdrawn.

Claims Rejection – 35 U.S.C. § 103

Claims 23-39 and 42 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Clarke, WO 01/05226 (hereinafter *Clarke*) in view of Vail III et al., U.S. Patent Publication No. 2004/0009245 (hereinafter *Vail*). Claims 40-41 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Clark* in view of *Vail* and further in view of Lemelson, U.S. Patent No. 4,856,509 (hereinafter *Lemelson*).

As noted by the Examiner, *Clarke* teaches p-methane-3,8-diol (PMD) has antiseptic, antibiotic, bactericidal and fungicidal properties while *Vail* teaches concentrated antiseptic botanical essential oils such as those from *Eucalyptus citriodora* have antiviral, antibacterial, and antifungal properties. The Examiner has concluded that PMD would be present in the essential oils of *Vail* as PMD is derived from *Eucalyptus citriodora.* Applicant respectfully submits the Examiner has erroneously concluded the antiviral activity disclosed in *Vail* is due to the presence of PMD.

i. PMD is not present in appreciable amounts in *Eucalyptus citriodora*

Applicant submits herewith a journal publication entitled "Repellent activities of stereoisomers of p-menthane-3,8-diols against Anopheles gambiae (Diptera: Culicidae)", Barasa et al., *Journal of Medical Entomology*, 2002, 39(5), 736-741 (hereinafter *Barasa*), cited as item CB by

the Applicant in the IDS filed on May 24, 2007. Applicant refers the Examiner to various parts of the article which explain that PMD is obtained by laboratory conversion of *Eucalyptus citriodora* constituents:

- Page 736, second column, first full paragraph.
- Page 737, first column, paragraph entitled "Synthesis of (+)- and (-)-trans-p-menthane-3,8-diols".
- Page 737, second column, paragraph entitled "Synthesis of (-)- and (+)-cis-p-menthane-3,8-diols".

It will be noted from *Barasa* that trace amounts of PMD are present in *Eucalyptus citiodora*: "Chiral GC analysis showed the presence of 60% citronellal, 24% racemic isopulegol, and 16% citronellol. **p-menthane-3,8-diol was detected only in trace amounts**." (see page 738, first paragraph, emphasis added). More specifically, the amount of PMD in *Eucalyptus citriodora* was found to be 0.32% (see page 738, first column, lines 5 and 6, and page 738, second column, Discussion section). Applicant submits that one of ordinary skill in the art would not attribute the antiviral properties of *Eucalyptus citriodora* to PMD, as PMD is present in trace amounts in *Eucalyptus citriodora.*

ii. Applicant derives PMD by chemical modification of the *Eucalyptus citriodora* extract

Referring to the instant application:

> "The PMD for use in the present invention may be a substantially pure form of the compound, or a crude extract, for example from a natural source. An example of a crude extract is a **PMD-rich extract derived from lemon eucalyptus by acid modification of lemon eucalyptus oil. The PMD can be produced by cyclisation of citronellal which is present in high concentration in lemon eucalyptus oil** (approximately 75% by weight)." (Page 2, paragraph 14, emphasis added)

Applicant discloses how to obtain PMD by chemical modification of citronellal which is a component of lemon eucalyptus oil. Acid modification of the essential oils is a process not disclosed by *Vail*. In the absence of acid modification, the essential oils do not contain appreciable amounts of PMD as discussed previously. Thus, in contrast to the assertions of the Examiner, it

would not have been obvious to one of ordinary skill in the art to utilize the compositions of *Clarke* as antiviral agents in view of *Vail*. In consideration of the foregoing, Applicant respectfully submits the pending claims are patentable over the cited references and are in condition for allowance.

Obviousness-Type Double Patenting

Claims 23-25, 28, 39, and 42 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 9 of U.S. Patent 7,189,421 (hereinafter the *'421* patent). MPEP § 804 II.B.1 outlines the requirements of a nonstatutory obviousness-type double patenting rejection:

> A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is **not patentably distinct** from the reference claim(s) because the examined application claim ... would have been obvious over the reference claim(s). ... A double patenting rejection of the obviousness-type ... is "analogous to a failure to meet the nonobviousness requirement of 35 U.S.C 103" except that the patent principally underlying the double patenting rejection is not considered prior art. ... Therefore, **the analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C 103 obviousness determination**. (Citations omitted)

The Applicant respectfully traverses this rejection because claims 23-25, 28, 30, and 42 of the instant application are patentable over claims 1-6 and 9 of the *'421* patent as the *'421* patent does not contain each and every element of the Applicant's claimed subject matter. As noted by the United States Supreme Court in *Graham v. John Deere Co. of Kansas City*, an obviousness determination begins with a finding that "the prior art as a whole in one form or another contains all" the elements of the claimed invention. *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 22 (U.S. 1966). Specifically, Applicant has recited the limitation that the virus comprises a lipid envelope, see claim 23. Similar limitations are not found in the claims of the *'421* patent.

Further, the Examiner has asserted that the *'421* patent is not conclusive to a population of patients with just fungal infections.[1] Thus, by administering PMD to a patient the patient would implicitly be destroying or inactivating the virus or treating a fungal infection. Applicant's currently amended claim 23 limits the viruses to those comprising a "lipid envelope." The Examiner's rejection assumes the lipid envelope is an inherent characteristic of the virus infecting the patient also afflicted with a fungal infection who is administered PMD. However, the existence of viruses lacking a lipid envelope is well established in the art (e.g. adenoviruses, papovaviruses). As stated *in re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)

> "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic."

Thus, in contrast to the Examiner's assertion, administration of PMD to a patient having both a fungal infection and a virus would not implicitly destroy or inactivate the virus. In consideration of the foregoing Applicant respectfully requests the rejection be withdrawn.

[1] Applicants note that the Examiner may be improperly considering the disclosure of the '421 patent rather than limiting the analysis to just the claims of the '421 patent. See MPEP§ 804.II.B.1.

CONCLUSION

Consideration of the foregoing amendments and remarks, reconsideration of the application, and withdrawal of the rejections is respectfully requested by Applicant. No new matter is introduced by way of the amendment. It is believed that each ground of rejection raised in the Office Action dated April 16, 2008 has been fully addressed. If any fee is due as a result of the filing of this paper, please appropriately charge such fee to Deposit Account Number 50-1515 of Conley Rose, P.C., Texas. If a petition for extension of time is necessary in order for this paper to be deemed timely filed, please consider this a petition therefore.

If a telephone conference would facilitate the resolution of any issue or expedite the prosecution of the application, the Examiner is invited to telephone the undersigned at the telephone number given below.

Respectfully submitted,
CONLEY ROSE, P.C.

Date: 8-18-08

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